



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thomas L. Meredith
Serial No.: 09/615,643
Filed: July 13, 2000
For: Composite Bone Material Implant And Prosthesis
Group Art Unit: 3738
Examiner: Brian E. Pellegrino
Attorney's Docket No.: N6089
Customer No.: 23456

#12
Declaration
S. Boyce
10/9/02
RECEIVED

OCT 2 - 2002

TECHNOLOGY CENTER R3700

REVISED DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Thomas L. Meredith, Applicant in the above-identified application, declares as follows:

(1) I have read and understand the Office Action mailed on March 21, 2002 in connection with the above-identified application. More specifically, I have read and understood the Boyce, et al. patent (U.S. 6,294,187), cited by the Examiner. I understand that the Boyce, et al. patent issued on September 25, 2001, and has an effective filing date of February 23, 1999.

(2) Attachment A is a photocopy of a sample of solid bone composite created and sealed prior to January 7, 1999. The solid bone composite sample comprises ground bone tissue, wherein the ground bone tissue includes an organic matrix and is substantially cortical bone tissue, and a binder selected from cyanoacrylate or fibrin, namely cyanoacrylate. This solid bone composite sample was produced by providing bone tissue, grinding the bone tissue to 125 to 850

microns in size, molding the ground bone tissue into a bone composite, introducing a cyanoacrylate binder to the bone composite, allowing the bone composite to cure, and refining the bone composite into the desired shape. This solid bone composite sample is pictured possessing a "half moon" shape in Attachment A. If needed, Applicant can provide the sealed solid bone composite sample to the Examiner.

(3) Attachment B is a memo dated January 19, 1999 describing a bone composite created using ground bone tissue and a Pasco-Fix binder. As noted on Attachment B, Pasco-Fix is a cyanoacrylate binder. The memo details conditions at which the bone composite was created and test results obtained with the bone composite.

(4) Attachment C is a description of the solid bone composite dated April 19, 2000. The description details the process of making a solid bone composite. The solid bone composite was made as of January 16, 1999 and comprises ground cortical bone tissue and a cyanoacrylate or fibrin binder. This solid bone composite sample was produced by providing demineralized cortical bone tissue, grinding the bone tissue, molding the ground bone tissue into a bone composite or matrix, introducing a cyanoacrylate or fibrin binder to the bone composite, curing the bone composite into a solid structure, and refining the bone composite into the desired shape.

(5) As can be substantiated by the attachments, prior to February 23, 1999, I conceived and reduced to practice the invention that is the subject matter of the above-identified application. It is clear that the present invention was

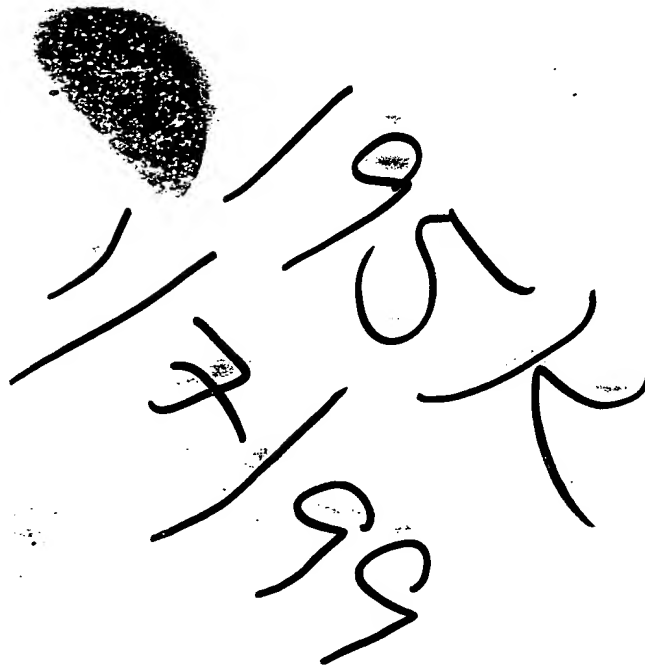
conceived and reduced to practice at least as early as January of 1999, a date prior to the effective filing date of the Boyce, et al. patent relied upon by the Examiner in the outstanding Office Action.

(6) I further state that the above statements were made with the knowledge that willful false statements and the like are punishable by fine and/or imprisonment, or both, under § 1001 of Title XVIII of the U.S. Code, and any such willful false statements may jeopardize the validity of this application or any patent resulting therefrom.

Thomas L. Meredith

Date

Heat sealed pack of Human Demineralized bone. Sealed on January 7th, 1999. This was first attempt of binding bone particles (125 to 850 microns) with Cyanoacrylate.



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ATTACHMENT A

Heat sealed pack with Human Demineralized bone. Full compacted disc at 195,000 psi, was snapped into two pieces. One half piece was saturated with Cyanoacrylate (CA) & left to dry. Other section eventually crumbled.

Tom Newell

1/19/1999

12:55.

11:45 Impregnate Semi Circular Bone Disc found at 192Kps
during last experiment, with PASCO-Fix "Organic Adhesive"
Disc observed @ 12:45 Disc stable unable to break with
excessive force.

will work to ID Adhesive to Tom / Jh P.

Thomas / Jh P.

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Pasco-Fix is Cyanoacrylate (CA)

T. Merdian 7/26/02

ATTACHMENT B

HUMAN BONE COMPOSITE DISCLOSURE

By: Thomas L. Meredith
Allograft Research Technologies, Inc.
Nashville, TN

April 19 2000

It is a known, that human demineralized bone tissue (DBM) when implanted will be readily received and hosted by another human being. When this matrix happens to be cortical bone, bone fusion will occur, this biocompatible and osteoinductive process allows the body to lay down native bone, which will eventually replace an implanted bone matrix. Today, the only other osteoinductive implants is allograft shapes that have been cut and shaped from cadaver donated bone. This is good, except that in many cases an exact shape can not be duplicated or more importantly early on fusion can not take place for lack of structural strength and density, causing the new implant to crush or even crumble. To assure a successful allograft implant, other supportive devices are needed in accompaniment, such as metal plates, screws and pins, but please be aware that metals and most polymers are not osteoinductive, and foreign to the body, causing extensive wear to existing bone, and eventual multiple surgeries.

With all of the above in mind, it stands to reason that an alternative implant device (s) is needed. Since cortical bone is the strongest and most abundant, It only makes good sense that it should be used as the basis of bone device research and technology.

So how do you make an implantable device, using human bone, and yet have the same strength factors of metals and plastics? How do you make a human bone device, and maintain all the factors needed for the human body to act as a host? A host that will allow total fusion of existing bone to bone? Theory and conceptual formulae started as far back as 1993, and actual manufacturing tests commenced on May 5, 1997.

First, de-mineralized cortical research bone is ground into various sizes (microns) and measured into batches (cubic centimeters). All dependant upon size and type of bone composite device.

Second, Special designed dies and/or molds (may be multiple) manufactured to match envelope dimensions of pre-selected bone devices (e.g., a bone pin), are placed into a special designed pressure vessel.

ATTACHMENT C

Third, Pre-measured ground bone batches are then dispensed into dies and/or molds. Pressure vessel is then locked into a safe and closed condition.

Fourth, Pressure vessel is inspected for tightness and possible pneumatic/hydraulic leaks. Externally generated pressure is then applied in a range from 14.7 psi (Atmospheric) to as high as 30,000 lbs. per square inch (psi). Amount of pressure depends solely on the level of bone density (particle compactness) desired. Formula used is: Pressure x Area = Force ($P \times A = F$), resulting in forces as high as 250,000 lbs. **Note:** Where high bone density is not a factor, 14.7 psi may be applied with a binder to mold applications. However, no binder and 15,000 psi may be applied to a die when high bone density and structural strength is required (e.g., a bone pin).

Fifth, After a pre-determined duration of time, pressure is relieved from pressure vessel and compressed bone matrix is removed. A pre-determined amount of binder (adhesive) is then applied, either by injection, spray or bath. Time, again is now a factor, (e.g.), fibrin (nature's biological adhesive) will necessitate an incubation period where cyanoacrylates can have a curing time as low as 8-10 seconds. **Note:** a combination of fibrin as well as other biocompatible binders is sometimes used with cyanoacrylates. However Cyanoacrylates is the main structural factor.

Last, After the semi finished bone composite has been removed from the die and/or mold, it is then inspected, and if further refinement is needed, it may then be machined, milled, ground or just shaped to tolerances by removing any excessive flashing.(e.g.), If finished device happens to be a pin, it may at this time be utilized as a fastener of other human bone in need of fixation.

In Summary:

With proper use of Pressure, Time, Temperature (insert max temp), binders (cyanoacrylate) and at times a combination of other biocompatible adhesives (fibrin). Qualities of high tensile strength metals can be mirrored with cortical bone composites, (e.g.), surface strength, core strength, and column strength.

It is now known that demineralized and ground cortical bone (DBM) can be formed into a solid device for the sole purpose of resorbable fixation in reparative orthopedic procedures.

At this time, it is totally feasible to manufacture a cortical bone composite, pin or screw. (Actual bone composite matrix , with all above claims, was produced on January 16, 1999).

END